**IN THE UNITED STATES DISTRICT COURT**
**WESTERN DISTRICT OF VIRGINIA**
**ABINGDON DIVISION**

**UNITED STATES OF AMERICA**

**v.** **CASE NO. 1:19cr00016**

**INDIVIOR INC. (a/k/a Reckitt Benckiser Pharmaceuticals Inc.) and INDIVIOR PLC**

**DEFENDANTS' REPLY IN SUPPORT OF MOTION FOR ISSUANCE OF PRE-TRIAL RULE 17(C) SUBPOENAS**

In its Response in Opposition to Indivior's Motion for Issuance of Pre-Trial Rule 17(c) Subpoenas (ECF No. 242) ("Response"), the government yet again seeks to prevent Indivior Inc. and Indivior PLC (collectively, "Indivior") from obtaining the key evidence they need to defend this case. In response to Indivior's previous Motion to Compel, the government asserted that it had no obligation to produce these materials because they are in the possession of agencies that were not involved in the investigation of this case. *See* Response in Opposition to Mot. to Compel at 5 (ECF No. 146); Response in Opposition to Objections to Magistrate Judge's Order at 2 (ECF No. 227). Now, the government is attempting to prevent Indivior from obtaining narrow categories of critical documents directly from these key agencies, and as a result, seeking to deny Indivior *any* meaningful access to the documents that are vital to its defense.

Contrary to the government's illogical assertion, Indivior is in no way using its proposed Rule 17(c) subpoenas to delay the trial in this case. Instead, it is requesting the pre-trial return of these key agency documents to *prevent* any delay that could result from the return of the

documents at trial.[1] In fact, it is the government that is attempting to deny Indivior any timely access to these records. Under Rule 17, Indivior does not need advance court permission to subpoena these same agencies for the same documents, returnable on the first day of trial. *See, e.g.*, *United States v. Beckford*, 964 F. Supp. 1010, 1018 (E.D. Va. 1997) (explaining that "a financially able party . . . need not seek leave of court by motion before issuance of a Rule 17(c) trial subpoena duces tecum"). Thus, the only point of the government's opposition is to deny Indivior the documents in time for Indivior to make effective use of them at trial.[2]

The government's attempt to obtain a tactical advantage by strategically blocking Indivior's access to these documents in advance of trial without meaningfully addressing the substance of the specific requests should not be permitted. Indivior respectfully requests that the Court order the Clerk's Office to issue the subpoenas attached to its Memorandum in Support of Motion for Issuance of Pre-Trial Rule 17(c) Subpoenas (ECF No. 230-1 through 230-11) to allow Indivior to inspect the materials and prepare its defense in advance of trial.

## ARGUMENT

In its opening brief, Indivior explained, on a request-by-request basis, the ways in which each proposed subpoena meets the standard set forth in *United States v. Nixon*, 418 U.S. 683

[1] Indivior acted expeditiously in filing its Motion for Issuance of Pre-Trial Rule 17(c) Subpoenas after its Motion to Compel was denied. It should be clear to the government that Indivior is not seeking to delay trial through this Motion given that it received Indivior's written request for many of these same documents on April 24, 2019, just 15 days after the Indictment was filed. *See* Mem. in Support of Def. Mot. to Compel, Ex. A (ECF No. 118-1).

[2] Without providing any support for its ability to do so, the government states in its Response that it "reserves the right to move to quash [the subpoenas] under Rule 17(c)(2) based on undue burden, or for other reasons." Response at 5 n.2. But it is the subpoena recipient—not the prosecution—that is able to assess the burden of responding to the subpoena and to seek post-issuance court intervention if necessary. *See, e.g.*, *United States v. Modi*, No. 01-cr-00050, 2002 WL 188327, at *1 (W.D. Va. Feb. 6, 2002) (distinguishing between the government's "right to be heard on a motion presented for the court's consideration" and the government's rights, or lack thereof, when a third-party subpoena has already been issued). The prosecution has already made clear its position that the relevant agencies are not under its control here.

(1974) for pre-trial issuance under Rule 17(c). *See* Def. Mem. in Support of Mot. for Issuance of Pre-Trial Rule 17(c) Subpoenas at 4-21 (ECF No. 230). In its Response, rather than addressing the specific requests as they are written, the government re-frames Indivior's requests to omit the fulsome context that appears in the requests themselves and in Indivior's opening brief, and creates a chart listing the "scope" of each request as it has been re-defined by the government. *See, e.g.*, Response at 4. The government then asserts, on a categorical basis, that the requests do not meet the standards for pre-trial issuance in this Circuit. But the individualized context of each request is critical to understanding the specific nature and relevance of the requested materials and makes clear Indivior is not undertaking a fishing expedition with only a glimmer of hope that it will uncover something useful to its defense. The following examples illustrate the government's strategic omissions, and demonstrate that Indivior's targeted requests for documents known to be in the possession of these agencies meet the relevancy, admissibility, and specificity requirements set forth in *Nixon*.

## I. Requests directed to DEA, SAMHSA, and relevant state agencies for specific records tied to physicians central to the Indictment

The Superseding Indictment alleges that Indivior "did aid, abet, counsel, command, induce, and procure physicians . . . who they knew were prescribing buprenorphine-containing drugs to more patients at a time than allowed by federal law (*i.e.*, the DATA), at daily doses higher than 24 mgs of buprenorphine (*i.e.*, in excess of the maximum dose of any demonstrated additional clinical advantage), and in a careless and clinically unwarranted manner, to switch their prescribing to Suboxone film." Superseding Indictment ¶ 97 (ECF No. 115); *see also id.* ¶¶ 98-143. The Superseding Indictment specifically alleges that Indivior aided and abetted four physicians "it knew were issuing careless, clinically unwarranted opioid prescriptions." *Id.* ¶¶ 102-12 (Doctor A); ¶¶ 113-27 (Doctors B & C); ¶¶ 128-43 (Doctor D). And it alleges that

Indivior aided and abetted these physicians by including them in Indivior's "Here to Help" physician referral program, *id.* ¶ 98, and providing them with "marketing materials, billing advice, and access to lunch and dinner events," *id.* ¶ 99.

Putting to one side the fact that the Superseding Indictment does not allege that these physicians committed health care or wire fraud or any other kind of criminal offense by prescribing in a "careless or clinically unwarranted manner," the nature of the physicians' prescribing practices continues to play a central role in the government's case, *see, e.g.*, Tr. of Oct. 1, 2019 Hearing at 42-43, 45 (ECF No. 205) (insisting that the allegations regarding physicians who prescribe in a "careless and clinically unwarranted manner" are "part of the conspiracy and . . . part of the fraud"). As a result, the evidence regarding the agencies' understandings of the physicians' prescribing practices and action or inaction as a result of those practices is a critical aspect of the case and a key part of Indivior's defense. Indivior is thus seeking to serve each of the agencies responsible for overseeing the physicians' prescribing practices with subpoenas requesting the files for the specific physicians that are central to these claims.

The government does not contest the agencies' oversight function as to the physicians who are featured in the Superseding Indictment. Instead, the government contends in its Response that (1) there is no "reason to believe that every agency action or inaction regarding a doctor makes it more or less probable that the doctor issued clinically unwarranted prescriptions" and (2) the actions of the DEA or State Boards, or lack thereof, are not relevant to Indivior's state of mind in this case. *See* Response at 7-8. The government is wrong on both points.

First, the requested records will show whether the agencies charged with monitoring the physicians' prescribing practices viewed any of the physicians' practices to be actionable, which

is relevant to any purported claim that Indivior aided and abetted the physicians in committing a crime. If the Drug Enforcement Administration ("DEA"), the Substance Abuse and Mental Health Services Administration ("SAMHSA"), or any of the relevant state medical or pharmacy boards ever received complaints about or investigated these physicians, the action or inaction by the relevant agency will reflect its view of the physician's conduct, which is critical evidence given that it is the agencies, and not Indivior, that have the ability to remedy physician misconduct. Even if, like in the case of Doctor D, an agency action relates to an issue other than the physician's Suboxone prescribing practices, that evidence will allow Indivior to defend any claim made by the government that Indivior aided and abetted a physician in committing a completely unrelated crime. *See* Superseding Indictment ¶ 143.

Second, the action or inaction taken by any of these agencies is certainly a relevant reflection of Indivior's state of mind during its interaction with these physicians over time. As a baseline, Indivior understood that each of the relevant physicians had valid DEA registrations, SAMHSA practitioner waivers, and state licenses. And Indivior had no obligation or ability to take action against the physicians if they observed any questionable practices. Instead, Indivior had to trust that the agencies charged with licensing and registering these physicians would oversee and assess the physicians' conduct and, where appropriate, take action to remedy any misconduct. The requested agency documents focused on these physicians will provide the complete picture of whether the government itself ever actually considered the relevant physicians' prescribing practices to be problematic and how, if at all, that impacted Indivior's baseline understanding of the physicians' standing as eligible prescribers of its products.

In addition to underplaying the relevance of these materials, the government overstates *Nixon*'s admissibility requirement, suggesting that Indivior must prove, at this stage, that every

document that will be produced in response to the subpoenas will be admitted at trial. The Fourth Circuit has made clear that is not the case. Instead, "it is only required that a good faith effort be made to obtain evidence" through the Rule 17(c) process. *In re Martin Marietta Corp.*, 856 F.2d 619, 622 (4th Cir. 1988). That is what Indivior intends to do through the issuance of the proposed subpoenas. In the case of the agency materials relating to the physicians, Indivior believes—as it does with the other agency records—that the materials produced will be admissible as relevant non-hearsay evidence or under Federal Rule of Evidence 803(6) as a record of the agency's regularly conducted activity or to show the absence of any record of such activity.

Finally, the government takes issue with the specificity of Indivior's requests for the agency files tied to these physicians. But the cases the government cites in support are distinguishable, and make clear that it is permissible for a defendant to seek sharply drawn categories of documents comprised of relevant materials. *See, e.g.*, *United States v. Ging-Hwang Tsoa*, No. 1:13-cr-137, 2013 WL 5837631, at *2 (E.D. Va. Oct. 29, 2013) ( "[T]he specificity requirement announced in *Nixon* is designed to ensure that the use of trial subpoenas is limited to securing the presence at trial of particular documents *or sharply defined categories of documents*." (quoting *United States v. Crosland*, 821 F. Supp. 1123, 1129 (E.D. Va. 1993) (emphasis added)). Here, Indivior is seeking, with specific reference to the physicians' DEA numbers and state license numbers, only the documents that are tied directly to the physicians who are central to the government's claims and the agencies' oversight of and action or inaction taken as to those physicians.[3] Given the clearly defined roles of these agencies in the oversight

[3] Specifically, Indivior is seeking the records relating to the four physicians who are directly referenced in the Indictment as Doctors A through D as well as three other physicians whom Indivior reported to the government.

of these physicians, there will not be any documents within this sharply defined category that fall outside of what is directly relevant to this case. *Cf. Ging-Hwang Tsoa*, 2013 WL 5837631, at *1-2 (considering a request for all documents related to a number of real estate transactions through which the defendant hoped to identify a narrower set of "several documents" she thought would be located within the files); *United States v. Kipp*, No. 3:15-cr-244, 2016 WL 7209581, at *2-3 (W.D.N.C. Dec. 9, 2016) (considering three subpoenas ranging in length from six to nine pages and including requests for all documents and communications on a number of topics, apparently without an accompanying explanation of why such categories were appropriately tailored in the context of the charged conduct in the case).

## II. Records from CDC employees known to have analyzed and expressed opinions regarding pediatric exposure

Another set of requests included in one of Indivior's proposed subpoenas seek the documents underlying the specific opinions expressed by employees of the Centers for Disease Control ("CDC") regarding the relative risk of pediatric exposure for certain buprenorphine products. *See* Def. Mem. in Support of Mot. for Issuance of Pre-Trial Rule 17(c) Subpoenas at 16-18. In 2016, multiple CDC employees published findings from a study regarding the rates of pediatric emergency room visits for buprenorphine/naloxone ingestions, which dropped by two-thirds when prescriptions dispensed in unit-dose packaging increased to over 80%.[4] The government is aware of this study and the multiple CDC authors whose names appear on the face of the publication. Yet the government decided to interview and obtain only a limited selection of documents relating to the pediatric exposure issue from just one of the CDC representatives.

[4] Daniel S. Budnitz, et al., Centers for Disease Control and Prevention, Notes from the Field: Pediatric Emergency Department Visits for Buprenorphine/Naloxone Ingestion—United States, 2008-2015, 65 Morbidity & Mortality Wkly. Rep. 1148 (2016).

The government does not address Indivior's specific request for the records reflecting the analysis and views publicly expressed by the narrow set of named CDC employees who actively participated in the study. Instead, the government now claims, for the first time, that it does not know whether any such documents exist. *See* Response at 3. That representation is hard to believe, given that the government has interviewed and obtained a subset of documents from Dr. Daniel Budnitz, one of the authors to the study, and knows that Dr. Budnitz was not the sole author of the study.[5] The government also knows that Dr. Budnitz was not the sole agency representative who prepared for and attended a CDC-sponsored meeting of the Prevention of Overdoses and Treatment Errors in Children Taskforce ("PROTECT") where Indivior was invited to explain its decision to move to unit-dose packaging, in the hopes that "other drug manufacturers would move toward unit-dose packaging in their products to reduce child exposures."[6] Even with regard to Dr. Budnitz, the government knows that there are additional relevant documents available on these key issues at the CDC that it chose not to collect.[7]

The government cannot credibly suggest that it believes the multiple CDC authors to the pediatric exposure study worked in parallel to create that study out of thin air without ever discussing it before or since. Documents the government has produced in this case make clear there are more records available that are tied to the CDC's analysis of these issues.[8] And the

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[5] Department of Health and Human Services, Office of Inspector General, Report of Interview of Captain Daniel Budnitz, 2 (Mar. 13, 2019) (M2085-M2089_0000009) (hereinafter "Budnitz Interview Report"); Budnitz Interview Report Attachment F (M2085-M2089_0000001) (Mar. 13, 2019 Email from Budnitz to HHS Special Agent Jeff Overbeck attaching documents).

[6] *See* Budnitz Interview Report at 2; Budnitz Interview Report Attachment F (M2085-M2089_0000004) (PROTECT and PROTECT-Rx Meeting Participants, Nov. 1-2, 2012).

[7] *See* Budnitz Interview Report at 3 (indicating that the study was based on data from the National Electronic Injury Surveillance System that resides at the CDC); Budnitz Interview Report Attachment F (M2085-M2089_0000001) (Budnitz asking HHS Special Agent Overbeck to let him know if they need any other materials from him).

[8] *See, e.g.*, *supra* n.7.

records underlying the study, which reflect the CDC's own knowledge and view of the relative safety risks associated with buprenorphine products, are highly relevant to whether Indivior's statements regarding the risk of pediatric exposure were actually false as alleged in the Indictment.

To be clear, Indivior has not requested from the CDC any and all records and communications relating to the agency's analysis of pediatric exposure issues, as the government's Response might suggest or as Indivior might do in a civil case. Rather, the requests are narrowly tailored to a small set of specific individuals who either (1) actively participated in the study published in 2016 and who, like Dr. Budnitz, have records underlying the specific analysis addressed therein or (2) participated in PROTECT's consideration of the implementation of unit-dose packaging to reduce rates of pediatric exposure. The latter request is intended to complete the partial set of documents the government obtained from Dr. Budnitz on this topic during his government interview in March 2019.[9]

## III. Records reflecting the FDA's review of the specific promotional materials referenced in the Indictment and stated conclusions on pediatric exposure

The government's Response also suggests that all of Indivior's requests directed to the Food and Drug Administration ("FDA") amount to blind attempts to obtain general discovery regarding non-descript submissions to the agency or purportedly irrelevant policies. *See, e.g.*, Response at 6, 9. Yet again, the government does not attempt to address the requests as they are written in the subpoenas, which reveal the narrowly targeted nature of the requests tied to specific allegations contained within the Indictment.

[9] Budnitz Interview Report Attachment F (M2085-M2089_0000001) (Mar. 13, 2019 Email from Budnitz to HHS Special Agent Overbeck attaching documents).

For example, Indivior's first request to the FDA seeks production of the records reflecting the FDA's Office of Prescription Drug Promotion's ("OPDP") receipt and review of specific promotional or marketing materials for Suboxone Film that are addressed in the Indictment. *See* Def. Mem. in Support of Mot. for Issuance of Pre-Trial Rule 17(c) Subpoenas at 10-11. This request is tied directly to the claim that between 2010 and 2019, Indivior distributed certain marketing materials containing purportedly false and fraudulent representations regarding Suboxone Film. *See* Superseding Indictment ¶ 76, p. 40. The precise promotional or marketing materials included in Indivior's request match those explicitly referenced in the Indictment as allegedly containing false or fraudulent representations. *See id.* ¶ 76.

Given that the OPDP is responsible for "reviewing prescription drug advertising and promotional labeling to ensure that the information contained in these promotional materials is not false or misleading,"[10] the OPDP's review of the specified materials would have been done for the very purpose of determining whether they are false or misleading. The OPDP's determination of whether the marketing materials were false or misleading is, to state the obvious, directly relevant to Indivior's defense of the government's claim that the documents contained "materially false and fraudulent statements and representations." *See id.*

Similarly, Indivior is requesting from the FDA the records underlying the conclusions of its divisions and offices that "Suboxone film in unit-dose packaging poses a lower overall risk of accidental pediatric exposure than Suboxone tablets in multi-dose packaging" and its recommendation to generic buprenorphine manufacturers to voluntarily switch to unit-dose packaging for their buprenorphine-containing products. *See* Def. Mem. in Support of Mot. for

[10] *The Office of Prescription Drug Promotion (OPDP)*, FDA, https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp (last visited Dec. 18, 2019).

Issuance of Pre-Trial Rule 17(c) Subpoenas at 13-15. Indivior did not create these requests out of whole cloth. Instead, they are tied directly to information contained in documents produced in this case showing that the FDA analyzed these issues and prepared and provided advice to generic manufacturers in light of its conclusions.[11] As with the records from the CDC, these materials requested from the FDA are directly relevant to, and indeed will directly undermine, the government's claims that Indivior made *false* statements that Suboxone Film was safer and less susceptible to pediatric exposure than other similar drugs.

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Although these are only examples of the narrowly crafted requests contained within Indivior's proposed pre-trial Rule 17(c) subpoenas, they highlight the necessity of considering the context within the requests themselves and contained within Indivior's opening brief (ECF No. 230). The government's wholesale objection to the subpoenas, without any consideration of the actual requests contained therein, cannot support the denial of Indivior's right to obtain the critical evidence it needs to supports its defense. The requests, all of which meet the factors outlined in *Nixon*, must be assessed on an individual basis, taking into consideration the actual language contained within the subpoena and the supporting information that has led to Indivior's understanding that the specific requested records are in the possession of these agencies and that each response will lead to the production of highly relevant, admissible evidence.

[11] Citizen Petition Response from Food & Drug Admin. Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology (Feb. 14, 2012) (RBP0114_19147715); Citizen Petition Response from Division of Anesthesia, Analgesia, and Addiction Products (Dec. 6, 2012) (RBP0114_19147735); Citizen Petition Response from Division of Medication Error Prevention and Analysis (Feb. 14, 2013) (RBP0114_19147756-57); Citizen Petition Response from Division of Epidemiology (Feb. 14, 2013) (RBP0114_19147802); Buprenorphine Prod. Mfrs. Grp. (BPMG), Meeting Minutes of FDA Call on BTOD REMS Submission 3-5 (Apr. 9, 2013) (M2058_0000001).

## CONCLUSION

For the foregoing reasons, and for the reasons stated in its Memorandum in Support of Motion for Issuance of Pre-Trial Rule 17(c) Subpoenas, Indivior respectfully requests that the Court grant its Motion and order the issuance of the subpoenas attached to its Memorandum as Exhibits A-K. On account the government's wholesale objection to the proposed subpoenas, Indivior also respectfully requests a hearing on this Motion to further address any questions on the specific requests contained within its proposed subpoenas.

Dated: December 18, 2019

Respectfully submitted,

INDIVIOR INC. (a/k/a Reckitt Benckiser Pharmaceuticals Inc.) and INDIVIOR PLC

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**CERTIFICATE OF SERVICE**

I hereby certify that I caused the foregoing to be presented to the Clerk of the Court for filing and uploading to the CM/ECF system, which will send notification of such filing to all counsel of record, on this 18th day of December, 2019.

/s/ Thomas J. Bondurant, Jr.
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